K002548

MAR - 6 2001

APPENDIX C – 510(K) SUMMARY

Fetal Assist™

Submitter's Name: Ms Audrey A. Witko,
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Name of Device: **Fetal Assist**

Manufactured by: Huntleigh Diagnostics Ltd
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:
B.J.Colleypriest
Telephone N°: 011-442-920-485885
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Date of summary: 14 August, 2000

Classification Name: Fetal Ultrasonic Monitor and Accessories (21 CFR § 884.2660)

Predicate Device: BABY DOPPLEX 4000, (BD4000), K990569.

K002548

Device Description

The FETAL ASSIST is a modular product that provides the clinically trained professional with a portable antepartum fetal monitor that produces fetal cardiotocographs (CTGs).

CTG traces are displayed in real time on the Liquid Crystal Display (LCD) which is integral to the Host Unit. The CTG's are stored within the integral memory of the Host Unit and can be reviewed or downloaded to an external printer and/or central location.

Power to energise the system is supplied by a stand-alone rechargeable battery pack. Alternatively, the Assist can be powered from the AC-powered supply via a power adapter.

Intended use

The FETAL ASSIST is suitable for use in all conventional antepartum fetal monitoring applications from a gestation age of approximately 26 weeks. It is particularly intended for use in the following specific areas:-

- Antenatal monitoring in the hospital, doctors office, health clinic, home or community.
- External Labour monitoring.
- Waterbirth monitoring using optional waterproof transducers

The FETAL ASSIST is a prescription device for use by clinically trained professionals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Mr. B. J. Colleypriest
Technical co-ordinator
Huntleigh Diagnostics Ltd.
35 Portmanmoor Road
Cardiff
CF24 5HN
UNITED KINGDOM

Re: K002548
Fetal Assist
Dated: December 1, 2000
Received: December 6, 2000
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Colleypriest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David A. Segerson

David A. Segerson
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

APPENDIX E – INDICATIONS FOR USE SUMMARY

510(k) Number (if known): K002548

Device Name: **Fetal Assist**

Indications for Use

The FETAL ASSIST is an antepartum and intrapartum fetal monitor. It is intended for use in the following specific areas:

Antenatal monitoring in the hospital, home, doctors office or health clinic by the healthcare professional.

Intrapartum monitoring with tocotransducer (for uterine contractions) and ultrasound transducer (for fetal heart rate)

The monitor can accept a waterproof ultrasound transducer for waterbirth monitoring

The FETAL ASSIST is a prescription device for use by clinically trained professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002548

Prescription Use ____✖____ OR Over the counter use _____

(Per 21 CFR 801.109)